Medicare Learning Network
MLN Matters
CMS Centers for Medicare & Medicaid Services
Information for Medicare Fee-for-Service Health Care Professionals

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Note: This article was changed on December 19, 2006 to specify that the $100,000 annual ceiling for passive laboratories must be exceeded by $25,000 or more to be terminated, as described on page 3. All other information remains the same.

NEWS FLASH	Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting http://www.cms.hhs.gov/NationalProvIdentStand/ on the CMS web site.

Laboratory Competitive Bidding Demonstration

Provider Types Affected

Physicians and hospitals (TOB 14X only) who bill Medicare carriers, fiscal intermediaries (FIs), or Part A/B Medicare Administrative Contractors (A/B MACs) for clinical laboratory tests performed for Medicare Part B beneficiaries who live within the competitive bidding demonstration area (CBA) sites

Background

Section 302(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) requires the Centers for Medicare & Medicaid Services (CMS) to conduct a demonstration project on the application of competitive acquisition for payment of most clinical laboratory services that would otherwise be payable under the Medicare Part B fee schedule.

Under this statute, pap smears and colorectal cancer screening tests are excluded from this demonstration. Requirements under the Clinical Laboratory

Disclaimer

1. ***Please note that the demonstration design described in Transmittals R49DEMO and R50DEMO, which provide instructions to Medicare contractors for the implementation of a CMS laboratory competitive bidding demonstration, is a proposed design and has not yet received final approval from the Office of Management and Budget.***

Improvement Amendments (CLIA), as mandated in section 353 of the Public Health Service Act, are applicable.

The payment basis determined for each CBA will be substituted for payment under the existing clinical laboratory fee schedule. Multiple winners are expected in each CBA.

Key Points

This article and Change Request (CR) 5359 provides instructions for the implementation of a laboratory competitive bidding demonstration. The requirements specified in this article and CR5359 are in preparation for the implementation of the demonstration in the first CBA on April 1, 2007.

- The project will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the zip code of the beneficiary's residence.
- Hospital inpatient testing is covered by Medicare Part A and is therefore exempt from the demonstration.
- Physician office laboratory (POL) testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department.
- CMS will continue to pay POL patient and hospital outpatient laboratory services in accordance with the existing clinical laboratory fee schedule.

Required Bidders

Laboratory firms with $100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year (CY) 2005 for "demonstration tests" provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) will be required to bid in the demonstration.

These laboratory firms will be referred to as "required bidders."

Passive Laboratories

Small laboratories or laboratory firms with less than $100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBAs will not be required to bid in the demonstration. These laboratories are considered "passive" laboratories." Passive laboratories will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBA.

During the demonstration period, CMS will monitor the volume of services performed by passive laboratories to ensure that their annual payments under Medicare Part B for demonstration tests provided to beneficiaries residing in the demonstration sites do not exceed the annual ceiling of $100,000.

Passive laboratory firms exceeding the annual ceiling of $100,000 by $25,000 or more will be:

- Terminated from the demonstration project; and
- Will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.
- Laboratories or laboratory firms providing clinical laboratory services exclusively to beneficiaries with end stage renal disease (ESRD) residing in the CBA will not be required to bid in the demonstration. These laboratories are considers "passive-ESRD" laboratories. Passive-ESRD laboratories will be paid the laboratory competitive bidding demonstration fee schedule for Part B demonstration tests provided to ESRD beneficiaries residing in the CBA. During the demonstration period (April 1, 2007 through March 31, 2010, inclusive), passive-ESRD laboratories that expand their business to provide clinical laboratory services to non-ESRD beneficiaries residing in the CBA will be terminated from the competitive bidding demonstration.

Winners

Both required and non-required bidders that bid and win will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located). These laboratories will be labeled "winners."

Non-Winners

Both required and non-required bidders that bid and do not win will not be paid anything by Medicare (neither under the Part B clinical laboratory fee schedule nor under the competitively bid price) for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration. These laboratories will be labeled "non-winners."

Similarly, required bidders that do not bid will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.

Non-winner laboratories that furnish a demonstration test to a Medicare beneficiary residing in the CBA during the demonstration have no appeal rights when Medicare payment for the test is denied. Moreover, non-winner laboratories may not charge the beneficiary for Part B laboratory services.

Demonstration-Covered Laboratory Tests

Only the laboratory that performs the test may bill for the service and only winning or passive laboratories are eligible to receive the laboratory competitive bidding demonstration fee schedule payment for services covered under the demonstration.

Although non-winner laboratories may not bill either Medicare or the beneficiary for any demonstration-covered services, such laboratories may refer such services to a winner laboratory or a passive laboratory.

For all other tests (i.e., those not covered under the demonstration or for tests for beneficiaries not residing in the service area), all laboratories will be paid according to the clinical laboratory fee schedule and in accordance with Medicare payment policies.

Demonstration Sites

There are two demonstration sites and each site runs for three years with a staggered start of one year. The demonstration uses Metropolitan Statistical Areas (MSAs) to define the CBAs.

The residence status of beneficiaries will be determined by information in the Medicare system as of the date the claim is processed. The residence of the beneficiary receiving services must be in the same CBA as determined by review of a beneficiary's zip code of residence.

CMS will provide the contractors with a list of zip codes included in each MSA, which will be used to determine whether a beneficiary's residence is included in one of the CBAs.

The demonstration will set (competitively bid) fees in the demonstration areas for all tests paid under the Medicare Part B clinical laboratory fee schedule, with the exception of pap smears, colorectal cancer screening tests, and new tests added to the Medicare Part B clinical laboratory fee schedule during the course of the demonstration. Demonstration fees will be set for each service payable under the demonstration in each of the CBAs.

Only CLIA-certified laboratories will be allowed to participate in the demonstration.

Implementation

CR5359 is being implemented in multiple phases. The requirements specified in this instruction are for the implementation of the demonstration in the first CBA (CBA1).

During the first quarter of 2007, CMS will provide Medicare carriers, FIs, and A/B MACs with a national zip code pricing file identifying the zip codes included in the first CBA. Also, in that same timeframe, CMS will provide to the carriers, FIs, and A/B MACs a list of the laboratories eligible to participate in the first CBA demonstration ("winners" and passive laboratories) and a list of those laboratories not selected to participate in CBA1.

For covered demonstration laboratory services in CBA1 with dates of service between April 1, 2007, and March 31, 2010, Medicare will pay the laboratory competitive bidding demonstration fee schedule amounts for laboratory services on that schedule. For services not on the demonstration schedule, Medicare will pay based on the clinical laboratory fee schedule.

Claims submitted by non-winner laboratories for dates of service of April 1, 2007, through March 31, 2010, for Medicare beneficiaries in CBA1 will be denied using:

- Reason code 96 (non-covered charges);
- Remark code M114 (*This service was processed in accordance with rules and guidelines under the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. If you would like more information regarding this project, you may contact your local contractor*.); and

- Remark code N83 (No appeal rights. Administrative decision based on the provisions of a demonstration project.).

Using these same reason and remark codes, Medicare will reject any laboratory claims with a date of service between April 1, 2007, and March 31, 2010 with a modifier of "90" submitted by laboratories for demonstration-covered services provided to beneficiaries residing in the CBA, regardless of the referring laboratory's participation status.

Medicare will pay claims during the demonstration period submitted by non-demonstration laboratories for beneficiaries residing in the CBA who receive services outside of those areas (e.g., "snow birds") according to the laboratory competitive bidding demonstration.

Non-winning laboratories should know that Advance Beneficiary Notices (ABNs) and Notices of Beneficiary Exclusion from Medicare Benefits (NEMBs) are not to be used to transfer liability to beneficiaries when services under the demonstration are obtained at non-winner laboratories.

Line items for demonstration services and for non-demonstration services may be submitted on the same claim.

A subsequent CR will be issued with requirements to implement the demonstration in the second CBA (CBA2).

Medicare contractors will be prepared to begin processing claims under the laboratory competitive bidding demonstration in the first CBA on April 1, 2007. The tentative start date for the demonstration in the second CBA is April 1, 2008.

Remember that required and non-required bidders that bid and lose will be paid nothing under the Part B clinical laboratory fee schedule and will have no appeal rights for demonstration tests provided to beneficiaries residing in the CBAs, regardless of the location of the laboratory itself.

Implementation

The implementation date for this instruction is April 2, 2007.

Additional Information

Disclaimers

1. ***Please note that the demonstration design described in Transmittals R49DEMO and R50DEMO, which provide instructions to Medicare contractors for the implementation of a CMS laboratory competitive bidding demonstration, is a proposed design and has not yet received final approval from the Office of Management and Budget.***

2. This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

The official instructions issued to your Medicare carrier, FI, or A/B MAC regarding this change can be found at http://www.cms.hhs.gov/Transmittals/downloads/R50DEMO.pdf on the CMS web site.

If you have questions, please contact your Medicare carrier, FI, or A/B MAC at their toll-free number which may be found at: http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS web site.

Flu Shot Reminder

Flu season is here! Medicare patients give many reasons for not getting their flu shot, including—"It causes the flu; I don't need it; it has side effects; it's not effective; I didn't think about it; I don't like needles!" The fact is that out of the average 36,000 people in the U.S. who die each year from influenza and complications of the virus, greater than 90 percent of deaths occur in persons 65 years of age and older. You can help your Medicare patients overcome these odds and their personal barriers through patient education. Talk to your Medicare patients about the importance of getting their annual flu shot--and don't forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot. Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For more information about Medicare's coverage of adult immunizations and educational resources, go to CMS's web site: http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0667.pdf